

Information **EDGE**

Challenge what you think. Expand what you know.

Enhancing Post-Marketing Surveillance

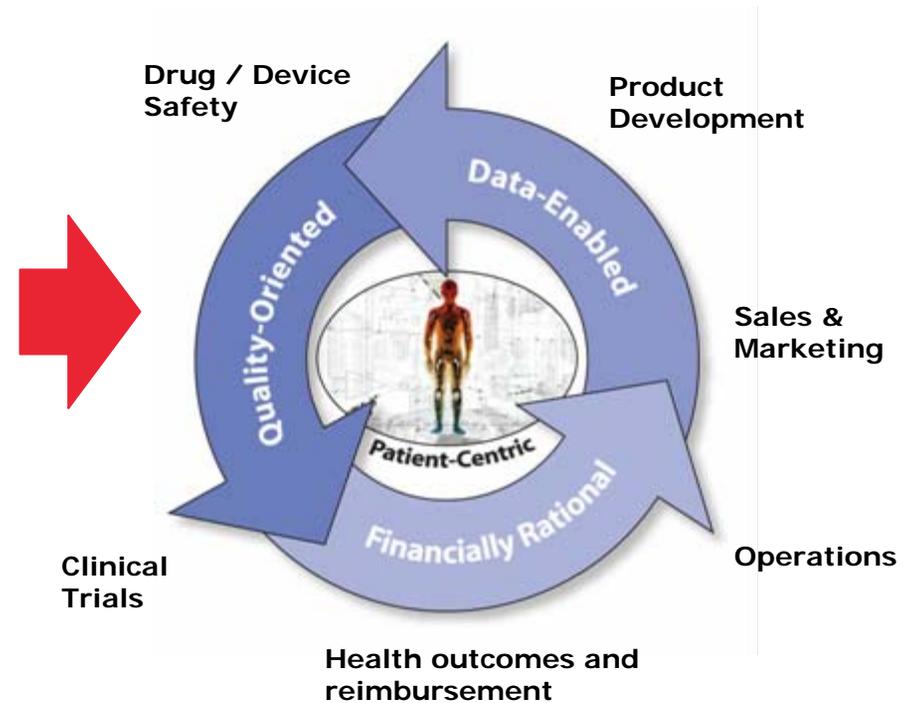
Adrian Thomas
Chief Safety Officer
Johnson & Johnson

HIT Will Accelerate Adoption Of A New Model

HIT Definition

- **Comprehensive, longitudinal, networked** medical information
- The **secure and confidential sharing and distribution** of medical information between health care system stakeholders
- The **advanced analysis** of medical data to:
 - Improve total quality of care
 - Enhance outcomes and safety
 - Reduce costs
 - Develop new products/services
 - Drive operational efficiency

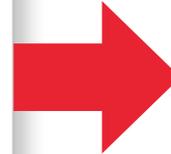
Touching Every Part of Health



The Effects Are Being Felt Across Industry Today

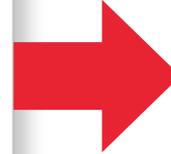
Current Headlines

The FDA is purchasing data from organizations with large volumes of electronic medical records, to perform its own observational safety research



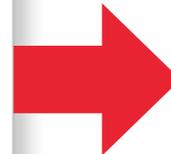
Regulators may discover safety issues regarding our products *faster than we do*

Vanderbilt is developing evidence on procedures, devices and drugs based on longitudinal patient data, and making it available at the point of care



A shift from formularies to protocols

CMS is partnering with AHRQ to mine electronic medical records from 13 academic medical centers to address drug and device outcomes and effectiveness



Coverage and reimbursement decisions may be based on data *we don't have access to*

Cisco, Intel and Oracle announce creation of a consortium to accelerate sharing and exchange of medical information using health information technologies



Threat of *disruption from unconventional competitors* greater than ever

HIT Principles: Critical For Acceptance

A FOCUS ON PROVIDERS AND PATIENTS

Our first responsibility is to doctors, nurses, and patients. A fully functional and integrated HIT environment will provide providers and patients with access to critical information, and foster continuous enhancement of the quality of care, delivering greater value to the system as measured by outcomes, safety, and cost.

PRESERVING PATIENT CONFIDENTIALITY

Patient confidentiality is paramount, and must be protected and maintained, even as information is continuously gathered. Patient specific data should only be made available to authorized care providers. At the same time, de-identified, aggregated data must be made widely available, for the betterment of health care.

OPEN PLATFORMS AND PROCESSES

Open technology standards and platforms must be developed through transparent and inclusive processes, enabling universal system compatibility. Those standards and platforms should be robust and scalable, to allow for ongoing innovation and improvement.

BROAD ACCEPTANCE BY CLINICIANS

Systems should be affordable, practical and easily integrated into existing work flows, to enable providers to meet their responsibility of providing patients with the highest quality of care. To achieve universal adoption by clinicians, benefits must be clearly demonstrated and articulated.

DRIVING INNOVATION

HIT should be employed to advance medical science and improve the efficiency of research and development, which will help bring innovative products to market faster.

INDUSTRY AND GOVERNMENT COOPERATION

All stakeholders – public and private – share responsibility for the development of open, accessible, robust HIT platforms for the benefit of all. The government should play a role in engaging stakeholders from all sectors to collaborate efficiently in the design and implementation of HIT.

Focus Within J&J: Four identified areas of focus

- **Evidence-based Medicine (EBM)**
 - Partner with provider organizations to shape how evidence is defined and created and to improve regulatory trust and approvals
- **Patient Safety**
 - Mine large volumes of electronic medical records to identify and respond to safety signals faster and drive efficiency and effectiveness
- **Research & Development**
 - Leverage new R&D process and tools for targeted studies, faster approvals, controlled launches and early identification of new indications/label changes
- **Consumer-oriented Solution**
 - Empower consumers with information and tools (e.g. personal health record) to make informed decisions regarding our products and ultimately leading to personalized medicine

M&N, MD&D and GA&P have all identified Evidence-based Medicine and Health Information Technology as strategic priorities